

**REMARKS**

After entry of this Amendment, the pending claims are: claims 7-12, 19-30, 33-44, 46-48 and 58-63. The Office Action dated April 16, 2008 has been carefully considered. Claims 31 and 32 have been canceled without prejudice. Claims 1-6, 13-18, 45 and 49-57 were previously canceled without prejudice. Claims 7-12, 19, 24-26, 28, 33, 37, 41, 44, 46 and 58 have been amended. Support for the amendments to claims 7-12, 19, 24-26, 28, 33, 37, 41, 44, 46 and 58 can be found throughout the Specification and Drawings and specifically in paragraph Nos. 53, 57, 64, 77, 80, 83, 86, 94, 98 and Fig. Nos. 3A, 4, 5B, 6B, 7, 8 and 10. Accordingly, no new matter has been added. Allowance of the pending claims in view of the above Amendments and the following remarks is respectfully requested.

In the Office Action dated April 16, 2008, the Examiner:

- rejected claims 19-24, 31, 32 and 36 under 35 U.S.C. 102(b) as being anticipated by United States Patent No. 6,471,711 to Irie *et al.* (“Irie”);
- rejected claims 7-12, 25-30, 33-35 and 58-63 under 35 U.S.C. 103(a) as being unpatentable over Irie; and
- rejected claims 37-44 and 46-48 under 35 U.S.C. 102(e) as being anticipated by United States Published Patent Application No. 2004/0092947 to Foley (“Foley”).

**INDEPENDENT CLAIM 7**

Independent claim 7 and claims 8-12 have been rejected as being unpatentable over Irie. Applicants respectfully traverse this rejection with respect to the above-listed claims, as amended.

Referring to Fig. 1, Irie discloses a device for guiding a puncture needle. The device 10 including a guide section 11 containing an insertion hole 12 for receiving a needle, a pole brace 17 substantially parallel to the guide section 11 and a cross beam 23 for connecting the guide section 11 to the pole brace 17, thereby spacing the guide section 11 from the pole brace 17. The brace 17 includes a leg 18 having a rubber support 19 for preventing slippage of the device 10, when the device 10 contacts the surface of a subject's body. The leg 18 is operatively associated with the brace 17 so that the height of device 10 can be adjusted.

Amended claim 7 is directed to a drill guide assembly and recites as follows:

a guide barrel for receiving a bone tool for creating a hole in bone; and  
**an alignment assembly associated with the guide barrel for aligning the bone tool with a selected first or second fastener hole of a bone plate, the alignment assembly comprising a location post configured to be at least partially received within a recess in the bone plate and a guide barrel housing within which the location post is slidably mounted, the guide barrel housing being in facing engagement with the guide barrel along its entire length, the recess being separate and distinct from the first and second fastener holes of the bone plate;**

wherein the guide barrel is not pivotable relative to the alignment assembly; and

wherein the location post is pivotable about the bone plate recess to allow the guide barrel to be selectively aligned with the first and second fastener holes; and

wherein the alignment assembly further comprising a housing having a first axial bore configured to slidably receive at least a portion of the location post; and

wherein the location post and housing further each comprising a distal end, the location post having a retracted position in which the location post distal end is located a first distance from the distal end of the housing, and an extended position in which the location post distal end is located a second distance from the distal end of the housing, wherein the second length is greater than the first length, **the location post includes a plurality of slots extending from a distal end thereof, the plurality of slots defining a plurality of resilient fingers so that insertion of the resilient fingers in the recess of the bone plate**

**compresses the resilient fingers within the recess thereby axially locking the drill guide to the bone plate; and**

wherein the alignment assembly further comprising a spring element disposed at least partially within a second axial bore in the housing to bias the location post to the extended position. (emphasis added).

Applicants respectfully submit that there is absolutely no disclosure, teaching, or suggestion in Irie of a drill guide comprising an alignment assembly and a guide barrel wherein the guide barrel is aligned with a selected first or second fastener hole of a bone plate and the alignment assembly includes a location post configured to be at least partially received within a recess in the bone plate. The recess is separate and distinct from the fastener hole of the bone plate. At most, Irie discloses a support for contacting a surface of the patient's body. *There is absolutely no disclosure, teaching or suggestion in Irie of a drill guide comprising a location post at least partially received within a recess in a bone plate.* Therefore, it is respectfully submitted that Irie does not disclose, teach, or suggest all of the limitations of independent claim 7.

Furthermore, Applicants respectfully submit that there is absolutely no disclosure, teaching, or suggestion in Irie of a drill guide comprising an alignment assembly including a location post configured to be at least partially received within a recess in the bone plate. The location post includes a plurality of slots extending from a distal end thereof. The plurality of slots define a plurality of resilient fingers so that insertion of the resilient fingers in the recess of the bone plate compresses the resilient fingers within the recess thereby axially locking the drill guide to the bone plate. At most, Irie discloses a support for contacting a surface of the patient's body. *There is absolutely no disclosure, teaching or suggestion in Irie of a drill guide*

Application No. 10/823,215  
Amendment filed July 15, 2008  
Response to Office Action dated April 16, 2008

*comprising a location post at least partially received within a recess in a bone plate, the location post including a plurality of resilient fingers for axially engaging the bone plate.* Therefore, it is respectfully submitted that Irie does not disclose, teach, or suggest all of the limitations of independent claim 7 for at least this reason as well.

In addition, Applicants respectfully submit that there is no disclosure, teaching, or suggestion in Irie of the claimed drill guide assembly including a guide barrel housing that is in facing engagement with the guide barrel along its entire length. Specifically, Irie discloses the guiding device wherein the pole brace 17 is separated from the guide section 11 along its entire length by the cross beam 23. Therefore, Applicants respectfully submit that Irie does not disclose, teach, or suggest these claimed features of amended claim 7 of the present application.

Based upon each of the above arguments, Applicants respectfully request withdraw of any rejection of amended claim 7 based upon Irie.

Furthermore, as claims 8-12 all depend from independent claim 7, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 8-12 is also respectfully requested.

#### **INDEPENDENT CLAIM 19**

Independent claim 19 and claims 20-24, 31, 32, and 36 have been rejected as being anticipated by Irie. Claims 25-30 and 33-35 have been rejected as being unpatentable over Irie. Applicants respectfully traverse these rejections with respect to the above-listed claims, as amended.

As previously stated above in connection with independent claim 7, Irie discloses a device for guiding a puncture needle. The device 10 including a guide section 11 containing an insertion hole 12 for receiving a needle, a pole brace 17 substantially parallel to the guide section 11 and a cross beam 23 for connecting the guide section 11 to the pole brace 17. The brace 17 includes a leg 18 having a rubber support 19 for preventing slippage of the device 10, when the device 10 contacts the surface of a subject's body. The leg 18 is operatively associated with the brace 17 so that the height of device 10 can be adjusted.

Amended claim 19 is directed to a surgical drill guide configured to engage an inner surface of a first or second fastener hole and a recess of a bone plate, and recites as follows:

a handle,

**a guide barrel having a length, a proximal end associated with the handle and a distal end engageable with the fastener hole**, the guide barrel further comprising a bore configured to receive a bone cavity forming tool; and

**an alignment assembly associated with the guide barrel for aligning the bone tool with the first or second fastener hole, the alignment assembly comprising a housing and a location post configured to be at least partially received within the recess, and having a length;**

wherein the guide barrel has a substantially longer length than the housing and the housing is integrally formed at the distal end of the guide barrel; and

wherein the location post is pivotable within the recess to allow the guide barrel to be selectively aligned with the first and second fastener holes so that the tool may be extended through the guide barrel to form a cavity in a bone underlying the selected fastener hole; and

**wherein the handle is detachably coupled to the proximal end of the guide barrel via a handle extension and a swivel assembly so that the handle can be rotatably positioned with respect to the guide barrel.** (emphasis added).

Applicants respectfully submit that there is absolutely no disclosure, teaching, or suggestion in Irie of a surgical drill guide comprising an alignment assembly and a guide barrel

Application No. 10/823,215  
Amendment filed July 15, 2008  
Response to Office Action dated April 16, 2008

wherein the guide barrel is aligned with a selected first or second fastener hole of a bone plate, the distal end of the guide barrel being engageable with the fastener hole and the alignment assembly including a location post configured to be at least partially received within a recess in the bone plate. At most, Irie discloses a support for contacting a surface of the patient's body. *There is absolutely no disclosure, teaching or suggestion in Irie of a drill guide comprising a location post at least partially received within a recess in a bone plate and a guide barrel engageable with a selected first or second fastener hole.* Therefore, it is respectfully submitted that Irie does not disclose, teach, or suggest all of the limitations of independent claim 19.

Furthermore, Applicants respectfully submit that there is absolutely no disclosure, teaching, or suggestion in Irie of a drill guide comprising a handle wherein the handle is detachably coupled to the proximal end of the guide barrel via a handle extension. Nor is there any disclosure, teaching, or suggestion of a swivel assembly so that the handle can be rotatably positioned with respect to the guide barrel. *There is absolutely no disclosure, teaching or suggestion in Irie of a detachable handle and swivel assembly.* Therefore, it is respectfully submitted that Irie does not disclose, teach, or suggest all of the limitations of independent claim 19 for at least this reason as well.

Accordingly, Applicant respectfully requests withdraw of any rejection of amended claim 19 based upon Irie.

Furthermore, as claims 20-30 and 33-36 all depend from independent claim 19, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 20-30 and 33-36 is also respectfully requested.

## INDEPENDENT CLAIM 37

Independent claim 37 and claims 38-44 have been rejected as being anticipated by Foley. Applicants respectfully traverse these rejections with respect to the above-listed claims, as amended.

Referring to Figs. 1 and 2, Foley discloses a guide assembly 20 including a handle 24 and a pair of guide members 25, 66. Each of the guide members 25, 66 includes a guide tube 27, 67 and an extension 28, 68 extending distally of the guide tube 27, 67, respectively. The extensions 28, 68 are contactable with the fastener holes in a plate to orient and align the passages 30, 70 formed in the guide tubes 27, 67 with the fastener holes formed in the plate.

Amended claim 37 is directed to a drill guide assembly and recites, *inter alia*, as follows:

a guide barrel having a tool receiving portion comprising a longitudinal bore having a bore axis, and an alignment assembly portion;

an alignment assembly comprising a guide barrel engaging portion, a housing and a location post having a post axis, wherein the housing and the guide barrel are monolithic,

**a bone plate having at least two bone screw holes and a positioning recess, the positioning recess being separate and distinct from the bone screw holes, the positioning recess being sized and configured not to receive a bone screw, the positioning recess configured to receive at least a portion of the location post, the center of the positioning recess being separated from the center of at least one of the bone screw holes by a first distance,**

wherein the bore axis is located a second distance from the location post axis, the first and second distances being substantially equal so that when the location post engages the bone plate recess, the bore is substantially coaxial with the at least one fixation hole; and

**wherein the guide barrel further includes a distal plate-engaging end comprising a nose portion configured to be received within one of the bone screw holes to align the longitudinal bore with the bone screw hole prior to drilling a hole.** (emphasis added).

Applicants respectfully submit that there is absolutely no disclosure, teaching, or suggestion in Foley of a drill guide assembly comprising a guide barrel having a distal plate-engaging end, an alignment assembly having a location post, and a bone plate wherein the bone plate includes a positioning recess for receiving at least a portion of the location post and at least two bone screw holes for receiving the distal plate-engaging end of the guide barrel. The positioning recess being separate and distinct from the bone screw holes and not sized and configured to receive a bone screw. At most, Foley discloses a guide assembly including a pair of guide members wherein each of the guide members includes a guide tube and an extension extending distally of the guide tube. The extensions being received within the fastener holes in the plate to orient and align the passages formed in the guide tubes with the fastener holes formed in the plate. *There is absolutely no disclosure, teaching or suggestion in Foley of a location post and a positioning recess configured to receive the location post wherein the positioning recess is separate and distinct from bone screw holes and the positioning recess is not sized and configured to receive a bone screw.* Therefore, it is respectfully submitted that Foley does not disclose, teach, or suggest all of the limitations of independent claim 37. Accordingly, Applicant respectfully requests withdraw of any rejection of amended claim 37 based upon Foley.

Furthermore, as claims 38-44 all depend from independent claim 37, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 38-44 is also respectfully requested.

## INDEPENDENT CLAIM 46

Independent claim 46 and claims 47 and 48 have been rejected as being anticipated by Foley. Applicants respectfully traverse these rejections with respect to the above-listed claims, as amended.

Similar to independent claim 37 discussed above, amended claim 46 is directed to a drill guide assembly and recites, *inter alia*, as follows:

a guide barrel having a tool receiving portion comprising a longitudinal bore having a bore axis, and an alignment assembly portion;

an alignment assembly comprising a guide barrel engaging portion, a housing and a location post having a post axis, wherein the housing and the guide barrel are monolithic,

**a bone plate having at least two fastener receiving holes and a drill guide positioning recess, the recess configured to receive at least a portion of the location post, the drill guide positioning recess being separate and distinct from the fastener receiving holes, the drill guide positioning recess being sized and configured not to receive a fastener**, the center of the drill guide positioning recess being separated from the center of at least one of the fastener receiving holes by a first distance,

wherein the bore axis is located a second distance from the location post axis as measured between the distal ends of the guide barrel and the location post, the first and second distances being substantially unequal so that when the location post engages the drill guide positioning recess, the bore is not coaxial with the at least one fastener receiving; and

**wherein the guide barrel further includes a distal plate-engaging end comprising a nose portion configured to be received within one of the fastener receiving holes to align the longitudinal bore with the fastener receiving hole prior to drilling a hole.**(emphasis added).

Applicants respectfully submit that there is absolutely no disclosure, teaching, or suggestion in Foley of a drill guide assembly comprising a guide barrel having a distal plate-engaging end, an alignment assembly having a location post, and a bone plate wherein the bone plate includes a drill guide positioning recess for receiving at least a portion of the location post

Application No. 10/823,215  
Amendment filed July 15, 2008  
Response to Office Action dated April 16, 2008

and at least two fastener receiving holes for receiving the distal plate-engaging end of the guide barrel. The positioning recess being separate and distinct from the fastener receiving holes and not sized and configured to receive a fastener. At most, Foley discloses a guide assembly including a pair of guide members wherein each of the guide members includes a guide tube and an extension extending distally of the guide tube. The extensions being received within the fastener holes in the plate to orient and align the passages formed in the guide tubes with the fastener holes formed in the plate. *There is absolutely no disclosure, teaching or suggestion in Foley of a location post and a drill guide positioning recess configured to receive the location post wherein the positioning recess is separate and distinct from fastener receiving holes and the positioning recess is not sized and configured to receive a fastener.* Therefore, it is respectfully submitted that Foley does not disclose, teach, or suggest all of the limitations of independent claim 46. Accordingly, Applicant respectfully requests withdrawal of any rejection of amended claim 46 based upon Foley.

Furthermore, as claims 47 and 48 all depend from independent claim 46, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 47 and 48 is also respectfully requested.

## **INDEPENDENT CLAIM 58**

Independent claim 58 and claims 59-63 have been rejected as being unpatentable over Irie. Applicants respectfully traverse this rejection with respect to the above-listed claims, as amended.

As previously stated above in connection with independent claim 7, Irie discloses a device for guiding a puncture needle. The device 10 including a guide section 11 containing an insertion hole 12 for receiving a needle, a pole brace 17 substantially parallel to the guide section 11 and a cross beam 23 for connecting the guide section 11 to the pole brace 17. The brace 17 includes a leg 18 having a rubber support 19 for preventing slippage of the device 10, when the device 10 contacts the surface of a subject's body. The leg 18 is operatively associated with the brace 17 so that the height of device 10 can be adjusted.

Amended claim 58 is directed to a drill guide and recites, *inter alia*, as follows:

a guide barrel for receiving a bone tool for creating a hole in bone; and

**an alignment assembly associated with the guide barrel for aligning the bone tool with a selected first or second fastener hole of a bone plate, the alignment assembly comprising a location post having a longitudinal axis and configured to be at least partially received within a recess in the bone plate;**

wherein the location post is pivotable about the longitudinal axis and in the bone plate recess to allow the guide barrel to be selectively aligned with the first and second fastener holes;

the alignment assembly further comprising a housing having a first axial bore configured to slidably receive at least a portion of the location post; and

wherein the location post and housing further each comprising a distal end, the location post having a retracted position in which the location post distal end is located a first distance from the distal end of the housing, and an extended position in which the location post distal end is located a second distance from the distal end of the housing, wherein the second length is greater than the first length, **the location post includes a plurality of slots extending from a distal end thereof, the plurality of slots defining a plurality of resilient fingers so that insertion of the resilient fingers in the recess of the bone plate compresses the resilient fingers within the recess thereby axially locking the drill guide to the bone plate; and**

wherein the alignment assembly further comprising a spring element disposed at least partially within a second axial bore in the housing to bias the location post to the extended position. (emphasis added).

Applicants respectfully submit that there is absolutely no disclosure, teaching, or suggestion in Irie of a drill guide comprising an alignment assembly and a guide barrel wherein the guide barrel is aligned with a selected first or second fastener hole of a bone plate and the alignment assembly includes a location post configured to be at least partially received within a recess in the bone plate. At most, Irie discloses a support for contacting a surface of the patient's body. *There is absolutely no disclosure, teaching or suggestion in Irie of a drill guide comprising a location post at least partially received within a recess in a bone plate.* Therefore, it is respectfully submitted that Irie does not disclose, teach, or suggest all of the limitations of independent claim 58.

Furthermore, Applicants respectfully submit that there is absolutely no disclosure, teaching, or suggestion in Irie of a drill guide comprising an alignment assembly including a location post configured to be at least partially received within a recess in the bone plate. The location post includes a plurality of slots extending from a distal end thereof. The plurality of slots define a plurality of resilient fingers so that insertion of the resilient fingers in the recess of the bone plate compresses the resilient fingers within the recess thereby axially locking the drill guide to the bone plate. At most, Irie discloses a support for contacting a surface of the patient's body. *There is absolutely no disclosure, teaching or suggestion in Irie of a drill guide comprising a location post at least partially received within a recess in a bone plate, the location post including a plurality of resilient fingers for axially engaging the bone plate.* Therefore, it is respectfully submitted that Irie does not disclose, teach, or suggest all of the limitations of independent claim 58 for at least this reason as well.

Application No. 10/823,215  
Amendment filed July 15, 2008  
Response to Office Action dated April 16, 2008

Accordingly, Applicant respectfully requests withdraw of any rejection of amended claim 58 based upon Irie.

Furthermore, as claims 59-63 all depend from independent claim 58, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 59-63 is also respectfully requested.

### **CONCLUSION**

No fee is believed due for this submission. If, however, the Commissioner determines otherwise, the Commissioner is authorized to charge any fees which may now or hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please contact Applicants' attorney at the number listed below.

Respectfully submitted,

Date: July 15, 2008

/Giuseppe Molaro/  
Giuseppe Molaro  
Registration No. 52,039

---

For: Brian M. Rothery  
Registration No. 35,340

Attorney for Applicants  
Stroock & Stroock & Lavan LLP  
180 Maiden Lane  
New York, New York 10038  
(212) 806-6114